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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,900	08/01/2007	Hirofumi Koda	47487-0004-00-US	8312
55694	7590	11/16/2009	EXAMINER	
DRINKER BIDDLE & REATH (DC)			MI, QIUWEN	
1500 K STREET, N.W.				
SUITE 1100			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20005-1209			1655	
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			11/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/594,900	KODA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 September 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-5 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 29 September 2006 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/1/07;9/5/07</u> .   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

Claims 1-5 are pending. **Claims 1-5 are examined on the merits.**

### Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-10 of copending Application No. 10/587, 522. Although the conflicting claims are not identical, they are not patentably distinct from each other because a maca extract obtained by the extraction method, wherein a temperature of extracting solution is from 20-70 °C when Maca extract is extracted by adding aqueous solution containing ethanol to small pieces or powder of Maca in claims 5-10 of copending Application No. 10/587, 522 is not materially different from the claims under examination, namely, an oral skin moisturizer comprising an extract of a plant of the genus *Lepidium* of the family Cruciferae, thus claims 5-10 of copending Application No. 10/587, 522 ‘anticipate’ the Claims 1-5 of the instant application.

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-13 of copending Application No. 10/594, 905. Although the conflicting claims are not identical, they are not patentably distinct from each other because a method of improving cutaneous peripheral blood flow comprising administering the instantly claimed composition make the instantly claimed composition obvious, thus claims 6-13 of copending Application No. 10/594, 905 ‘anticipate’ the Claims 1-5 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Claim Objections**

Claim 4 is objected to because of the following informalities:

Claim 4 recites the limitation “the mixture” in line 3. There is insufficient antecedent basis for this limitation in the claim. Applicant might overcome the objection by recites “The oral skin moisturizer according to claim 3, wherein the maca extract is obtained by adding an aqueous ethanol solution to a crushed maca product **to form a mixture**, and maintaining the mixture at 40 to 85°C for extraction”.

### **Claim Rejections –35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 are rejected under 35 USC § 102 (b) as being anticipated by Zheng et al (US 6,267,995).

Zheng et al disclose extract of *Lepidium meyenii* roots (thus family Cruciferae) for pharmaceutical applications (thus a pharmaceutical product, thus the limitation of claim 5 is met) (see Title). Zheng et al teach contacting *Lepidium* plant material with an aqueous solvent comprising 90 vol % or more water (col 2, lines 60-67). Zheng et al also teach the term aqueous solvent means water or a single phase having an organic solvent that is miscible with water. Examples of miscible organic solvents include but not limited to methanol, ethanol, isopropanol etc (col 3, lines 27-33). For example the root of *Lepidium meyenii* is reduced to size to pieces having nominal dimensions between about 0.1 mm and 30 mm (crushed). The pieces of *Lepidium* plant material are contacted with aqueous solvent. Typically the contacting is conducted from 20-75 °C (thus overlapping with the claimed temperature 40-85 °C) (col 4, lines 35-40). Zheng et al further teach the *Lepidium* compositions used in the method of the present invention can be administered by any route. For the oral mode of administration, the compositions of the present invention are used in the form of tablets, capsules, chewing gum (thus oral), and the like (col 9, lines 55-65).

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 1-5 are rejected under 35 USC § 102 (e) as being anticipated by Cui et al (US 6,878,731).

Cui et al teach that roots of *L. meyenii* (thus family Cruciferae) having been cleaned with water are mixed or contacted with a first solvent, such as but not limited to ethanol (col 4, lines 18-23). Depending on the type of plant material used or its physical condition, it may be necessary to grind (crushed) it into a range 0.1-10 min (col 4, lines 25-30). In the extraction process the temperature of extraction is between 40-70 °C (thus overlapping with the claimed temperature 40-85 °C) (col 4, lines 35-40). Cui et al also teach that dried Maca roots are ground to powder and sold in drug stores in capsules as a medicine (thus a pharmaceutical product) and food supplement (thus the limitation of claim 5 is met) to increase stamina and fertility (col 1, lines 60-65).

Therefore, the reference is deemed to anticipate the instant claim above.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Examiner, Art Unit 1655